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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 47

**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	1614
Examiner Name	Polansky
Attorney Docket Number	29635-714.201

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/G.P./	1	US- 2002/0192299 A1	12-19-2002	Taneja et al.	
	2	US- 2003/0144306 A1	07-31-2003	Phillips	
	3	US- 2003/0215527 A1	11-20-2003	Phillips	
	4	US- 2004/0048896 A1	03-11-2004	Phillips	
	5	US- 2004/0058018 A1	03-25-2004	Phillips	
	6	US- 4,045,564	08-30-1977	Berntsson et al.	
	7	US- 4,182,766	01-08-1980	Krasso et al.	
	8	US- 4,255,431	03-10-1981	Junggren et al.	
	9	US- 4,337,257	06-29-1982	Junggren et al.	
	10	US- 4,359,465	11-16-1982	Ruwart	
	11	US- 4,414,216	11-08-1983	Kawakita et al.	
	12	US- 4,472,409	09-18-1984	Senn-Bilfinger	
	13	US- 4,508,905	04-02-1985	Junggren et al.	
	14	US- 4,544,750	10-01-1985	Brandstrom et al.	
	15	US- 4,620,008	10-28-1986	Brandstrom et al.	
	16	US- 4,636,499	01-13-1987	Brandstrom et al.	
	17	US- 4,725,691	02-16-1988	Brandstrom et al.	
	18	US- 4,738,974	04-19-1988	Brandstrom	
/G.P./	19	US- 4,786,505	11-22-1988	Lovgren et al.	

**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
/G.P./	20	CA 1,234,118	03-15-1988	Aktiebolaget Hassle		
	21	DE 19,752,843 C2	01-09-2003	Rango, D.		
	22	EP 0,005,129 A1	10-31-1979	Aktiebolaget Hassle		
	23	EP 0,005,129 B1	04-29-1981	Aktiebolaget Hassle		
	24	EP 0,308,515 A1	03-29-1989	Yoshitomi Pharmaceutical		
/G.P./	25	EP 0,308,515 B1	01-26-1994	Yoshitomi Pharmaceutical		

Examiner  
Signature

/Gregg Polansky/

Date  
Considered

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/G.P./	26	US- 4,853,230	08-01-1989	Lovgren et al.	
	27	US- 4,965,351	10-23-1990	Caruso et al.	
	28	US- 4,985,548	01-15-1991	Caruso et al.	
	29	US- 5,008,278	04-16-1991	Brandstrom et al.	
	30	US- 5,013,743	05-07-1991	Iwahi et al.	
	31	US- 5,019,584	05-28-1991	Brandstrom et al.	
	32	US- 5,025,024	06-18-1991	Brandstrom et al.	
	33	US- 5,039,806	08-13-1991	Brandstrom et al.	
	34	US- 5,045,321	09-03-1991	Makino et al.	
	35	US- 5,075,323	12-24-1991	Fain et al.	
	36	US- 5,093,132 A	03-03-1992	Makino et al.	
	37	US- 5,093,342 A	03-03-1992	Tomoi et al.	
	38	US- 5,106,862 A	04-21-1992	Briving et al.	
	39	US- 5,124,158 A	06-23-1992	Ruwart et al.	
	40	US- 5,215,974 A	06-01-1993	Alminger et al.	
	41	US- 5,219,870 A	06-15-1993	Kim	
	42	US- 5,232,706 A	08-03-1993	Palomo Coll	
	43	US- 5,244,670 A	09-14-1993	Upson et al.	
/G.P./	44	US- 5,288,506 A	02-22-1994	Spickett et al.	

FOREIGN PATENT DOCUMENTS						
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/G.P./	45	EP 0,040,639 A1	12-02-1981	Yoshitomi Pharm		
	46	EP 0,040,639 B1	05-30-1984	Yoshitomi Pharm		
	47	EP 0,237,200 B1	07-01-1992	Takeda Chemical		
	48	EP 0,244,380 A2	11-04-1987	Aktiebolaget Hassle		
	49	EP 0,244,380 B1	01-07-1993	Aktiebolaget Hassle		
/G.P./	50	EP 0,247,983 A2	12-02-1987	Aktiebolaget Hassle		

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/G.P./	51	US- 5,374,730 A	12-20-1994	Siemon et al.	
	52	US- 5,385,739 A	01-31-1995	Debregeas et al.	
	53	US- 5,386,032 A	01-31-1995	Brandstrom	
	54	US- 5,391,752 A	02-21-1995	Hoerner et al.	
	55	US- 5,395,323 A	03-07-1995	Berglund	
	56	US- 5,399,700 A	03-21-1995	Min et al.	
	57	US- 5,417,980 A	05-23-1995	Goldman et al.	
	58	US- 5,430,042 A	07-04-1995	Lindberg et al.	
	59	US- 5,447,918 A	09-05-1995	McCullough	
	60	US- 5,447,923 A	09-05-1995	Catrenich et al.	
	61	US- 5,470,983 A	11-28-1995	Siemon et al.	
	62	US- 5,504,082 A	04-02-1996	Kawakita et al.	
	63	US- 5,589,491 A	12-31-1996	Nakanishi et al.	
	64	US- 5,599,794 A	02-04-1997	Eek et al.	
	65	US- 5,629,305 A	05-13-1997	Eek et al.	
	66	US- 5,633,244 A	05-27-1997	Eek et al.	
	67	US- 5,639,478 A	06-17-1997	Makino et al.	
	68	US- 5,690,960 A	11-25-1997	Bengtsson et al.	
/G.P./	69	US- 5,693,818 A	12-02-1997	Von Unge	

FOREIGN PATENT DOCUMENTS						
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/G.P./	70	EP 0,247,983 B1	01-07-1993	Aktiebolaget Hassle		
	71	EP 0,248,634 A2	12-09-1987	Nippon Chemiphar		
	72	EP 0,248,634 B1	07-21-1993	Nippon Chemiphar		
	73	EP 0,308,515 B1	01-26-1994	Aktiebolaget Hassle		
	74	EP 0,315,964 A1	05-17-1989	Fujisawa Pharmaceutical		
/G.P./	75	EP 0,315,964 B1	01-07-1993	Laboratoires Pharmascience		

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Sheet 4 of

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First Named Inventor	Widder, et al.
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/G.P./	76	US- 5,714,504 B1	02-03-1998	Lindberg et al.	
	77	US- 5,714,505 B1	02-03-1998	Hasselkus	
	78	US- 5,731,002 B1	03-24-1998	Olovson et al.	
	79	US- 5,753,265 B1	05-19-1998	Bergstrand et al.	
	80	US- 5,766,622 B1	06-19-1998	Nelson	
	81	US- 5,776,765 B1	07-07-1998	Graham et al.	
	82	US- 5,798,120 B1	08-25-1998	Tomohisa et al.	
	83	US- 5,814,338 B1	09-29-1998	Veronesi	
	84	US- 5,817,338 B1	10-06-1998	Bergstrand et al.	
	85	US- 5,840,737 B1	11-24-1998	Phillips	
	86	US- 5,876,759 B1	03-02-1999	Gowan, Jr.	
	87	US- 5,877,192 B1	03-02-1999	Lindberg et al.	
	88	US- 5,879,708 B1	03-09-1999	Makino et al.	
	89	US- 5,883,102 B1	03-16-1999	Hamley et al.	
	90	US- 5,885,594 B1	03-23-1999	Nilsen et al.	
	91	US- 5,900,424 B1	05-04-1999	Kallstrom et al.	
	92	US- 5,929,244 B1	07-27-1999	Von Unge	
	93	US- 5,939,091 B1	08-17-1999	Eoga et al.	
/G.P./	94	US- 5,948,789 B1	09-07-1999	Larsson et al.	

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/G.P./	95	EP 0,338,861 B1	01-20-1993	Walton S.A.		
	96	EP 0,394,471 A1	10-31-1990	Yoshitomi-machi Chikugo-gun		
	97	EP 0,414,847 B1	09-08-1993	Aktiebolaget Hassle		
	98	EP 0,436,620 B1	08-10-1994	Morein, Bror		
	99	EP 0,452,697 A1	10-23-1991	Fujisawa Pharmaceutical		
/G.P./	100	EP 0,452,697 B1	12-06-1995	Fujisawa Pharmaceutical		

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	102	US- 5,958,955 A	09-28-1999	Gustavsson et al.	
	103	US- 5,962,022 A	10-05-1999	Bolt et al.	
	104	US- 5,965,162 A	10-12-1999	Fuisz et al.	
	105	US- 5,972,389 A	10-26-1999	Shell et al.	
	106	US- 5,979,515 A	11-09-1999	Olsson	
	107	US- 6,013,281 A	01-11-2000	Lundberg et al.	
	108	US- 6,017,560 A	01-25-2000	Makino et al.	
	109	US- 6,090,827 A	07-18-2000	Erickson et al.	
	110	US- 6,123,962 A	09-26-2000	Makino et al.	
	111	US- 6,124,464 A	09-26-2000	Hogberg et al.	
	112	US- 6,132,770 A	10-17-2000	Lundberg	
	113	US- 6,132,771 A	10-17-2000	Depui et al.	
	114	US- 6,136,344 A	10-24-2000	Depui et al.	
	115	US- 6,143,771 A	11-07-2000	Lindberg et al.	
	116	US- 6,147,103 A	11-14-2000	Anousis et al.	
	117	US- 6,150,380 A	11-21-2000	Lovqvist et al.	
	118	US- 6,162,816 A	12-19-2000	Bohlin et al.	
/G.P./	119	US- 6,166,213 A	12-26-2000	Anousis et al.	

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	121	EP 0,496,437 A2	07-29-1992	Aktiebolaget Hassle		
	122	EP 0,496,437 A3	07-29-1996	Aktiebolaget Hassle		
	123	EP 0,496,437 B1	07-29-1992	Aktiebolaget Hassle		
	124	EP 0,502,556 A1	09-09-1992	Aktiebolaget Hassle		
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 6 of

**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/G.P./	126	US- 6,183,776 B1	02-06-2001	Depui et al.	
	127	US- 6,248,363 B1	06-19-2001	Patel et al.	
	128	US- 6,274,173 B1	08-14-2001	Sachs et al.	
	129	US- 6,284,271 B1	09-04-2001	Lundberg et al.	
	130	US- 6,489,346 B1	12-03-2001	Phillips	
	131	US- 6,569,453 B2	04-27-2003	Linder et al.	
	132	US- 6,645,988 B2	11-11-2003	Phillips	
/G.P./	133	US- 6,699,885 B2	03-02-2004	Phillips	
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FOREIGN PATENT DOCUMENTS					
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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
/G.P./	134	EP 0,565,210 A2	10-13-1993	Aktiebolaget Hassle	
	135	EP 0,565,210 A3	06-07-1995	Aktiebolaget Hassle	
	136	EP 0,565,210 B1	11-17-1999	Astra Aktiebolag	
	137	EP 0,567,201 A2	10-27-1993	Aktiebolaget Hassle	
	138	EP 0,567,201 A3	07-06-1995	Aktiebolaget Hassle	
/G.P./	139	EP 0,567,201 B1	09-15-1999	Astra Aktiebolag	

Examiner  
Signature

/Gregg Polansky/

Date  
Considered

12/14/2007

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 47

**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

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IG.P./	140	EP 0,567,643 A1	11-03-1993	Yoshitomi Pharm		
↓	141	EP 0,587,659 B1	05-07-1997	British Technology Grp.		
↓	142	EP 0,636,364 B1	09-20-2000	McNeil-PPC, Inc.		
↓	143	EP 0,652,751 B1	10-23-1996	Astra Aktiebolag		
↓	144	EP 0,654,471 A1	05-24-1995	Eisai Co., Ltd.		
IG.P./	145	EP 0,654,471 B1	07-08-1998	Eisai Co., Ltd.		

**Examiner  
Signature**

/Gregg Polansky/

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Considered	

12/14/2007

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Sheet	9	of
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Art Unit	
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Attorney Docket Number	

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		Country Code <sup>2</sup> -Number <sup>4</sup> -Kind Code <sup>3</sup> (if known)	MM-DD-YYYY			
/G.P./	152	JP 03-48680 A	03-01-1991	Yoshitomi Pharmaceutical		
↓	153	JP 03-52887 A	03-07-1991	Yoshitomi Pharmaceutical		
	154	JP 03-163018 A	07-15-1991	Takeda Chem Ind Ltd.		
	155	JP 05-117268 A	05-14-1993	Yoshitomi Pharmaceutical		
	156	JP 05-194224 A	08-03-1993	Yoshitomi Pharmaceutical		
/G.P./	157	JP 05-194225 A	08-03-1993	Yoshitomi Pharmaceutical		

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Signature**

/Gregg Polansky/

<b>Date</b>	
<b>Considered</b>	

12/14/2007

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**Complete if Known**

Application Number	10/783,871
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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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Art Unit	Unit	Lesson	Activity	Assessment
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Examiner Name

Attorney Docket Number	29635-714.201
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Sheet	10	of	47
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## U. S. PATENT DOCUMENTS

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**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>4</sup> (if known)				
/G.P./	158	JP 05-255088 A	10-05-1993	Yoshitomi Pharm		
↓	159	JP 05-294831 A	11-09-1993	Aktiebolaget Hassle		
	160	JP 06-092853 A	04-05-1994	Fujisawa Pharm Co		
	161	JP 06-100449 A	04-12-1994	Yoshitomi Pharm		
	162	JP 07-033659 A	02-03-1995	Yoshitomi Pharm		
	163	JP 09-087110 A	03-31-1997	Yoshitomi Pharm		

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/Gregg Polansky/

Date Considered

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Sheet	11	of	47
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Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

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/G.P./	164	JP 10017470 A	01-20-1998	Yoshitomi Pharm		
↓	165	JP 10017471 A	01-20-1998	Yoshitomi Pharm		
	166	JP 2000-212180 A	08-02-2000	Welfide Corp		
	167	JP 2000-355540 A	12-26-2000			
	168	JP 45-039541 A	12-12-1970	Yoshitomi Pharm		
/G P /	169	JP 45-039543 A	12-12-1970	Yoshitomi Pharm		

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/Gregg Polansky/

Date  
Cons

12/14/2007

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Sheet 12

of 47

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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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**Art Unit**

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/G P /	170	JP 46-009580 A	03-11-1971	Yoshitomi Pharm		
↓	171	JP 46-009581 A	03-11-1971	Yoshitomi Pharm		
↓	172	JP 48-103567 A	12-25-1973	Japan Chem Ind KK		
↓	173	JP 49-005967 A	01-19-1974	Yoshitomi Pharm		
↓	174	JP 49-013172 A	02-05-1974	Yoshitomi Pharm		
/G P /	175	JP 49-020173 A	02-22-1974	Yoshitomi Pharm		

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↓	177	JP 49-041198 A	04-17-1974	Yoshitomi Pharm		
	178	JP 49-093537 A	09-05-1974	Yoshitomi Pharm		
	179	JP 49-095997 A	09-11-1974	Yoshitomi Pharm		
	180	JP 50-052065 A	05-09-1975	Yoshitomi Pharm		
/G.P./	181	JP 50-112373 A	09-03-1975	Yoshitomi Pharm		

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12/14/2007

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	14	of	47
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**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
/G.P./	182	JP 50-142565 A	11-17-1975	Yoshitomi Pharm		
↓	183	JP 51-016669 A	02-10-1976	Yoshitomi Pharm		
	184	JP 51-017268 A	02-12-1977			
	185	JP 51-131875 A	11-16-1976	Yoshitomi Pharm		
	186	JP 52-005769 A	01-17-1977	Yoshitomi Pharm		
/G.P./	187	JP 52-014776 A	02-03-1977	Yoshitomi Pharm		

Examiner  
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/Gregg Polansky/

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Considered	

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*(Use as many sheets as necessary)*

Sheet	15	of	47
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### Complete if Known

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

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		Country Code <sup>2</sup> *Number <sup>4</sup> *Kind Code <sup>3</sup> (if known)				
/G.P./	188	JP 52-097978 A	08-17-1977	Yoshitomi Pharm		
↓	189	JP 52-102416 A	08-27-1977	Okawara Mfg		
	190	JP 53-059675 A	05-29-1978	Yoshitomi Pharm		
↓	191	JP 55-019211 A	02-09-1980	Misui Toatsu Chem Inc		
	192	JP 56-061311 A	05-26-1981	Fujisawa Pharmaceutical		
/G.P./	193	JP 59-095997 A	06-02-1984	Hitachi Plant Kensetsu KK		

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Sheet	16	of	47
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Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

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		Country Code <sup>2</sup> *Number <sup>3</sup> *Kind Code <sup>4</sup> (if known)				
/G.P./	194	JP 61-221117 A	10-01-1986	Fujisawa Pharm		
↓	195	JP 62-145083 A	06-29-1987	Yoshitomi Pharm		
	196	JP 62-258316 A	11-10-1987	Haessel AB		
	197	JP 62-258320 A	11-10-1987	Haessel AB		
	198	JP 62-277322 A	12-02-1987	Takeda Chem Ind. Ltd.		
/G.P./	199	JP 62-283964 A	12-09-1987	Astra AB		

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Signature**

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Sheet 17

of 47

**Complete if Known**

Application Number	10/783.871
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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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**Art Unit**

Examiner Name

Attorney Docket Number	29635-714.201
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**U. S. PATENT DOCUMENTS**

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Sheet	18	of	47
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**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

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/G.P./	206	WO 00/10999 A2	03-02-2000	Astra Aktiebolag		
↓	207	WO 00/10999 A3	03-02-2000	Astra Aktiebolag		
	208	WO 00/15195 A1	03-23-2000	Nycomed Danmark		
	209	WO 00/26185 A2	05-11-2000	Curators of Uni. of Missouri		
	210	WO 00/26185 A3	05-11-2000	Curators of Uni. of Missouri		
/G.P./	211	WO 00/27366 A1	05-18-2000	Astrazeneca AB		

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12/14/2007

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 19

of 47

**Complete if Known**

Application Number	10/783,871
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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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**Art Unit**

Examiner Name

Attorney Docket Number	29635-714.201
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/G.P./	212	WO 00/28975 A2	05-25-2000	Astrazeneca AB		
↓	213	WO 00/28975 A3	05-25-2000	Astrazeneca AB		
↓	214	WO 00/30612 A1	06-02-2000	Astrazeneca AB		
↓	215	WO 00/35448 A1	06-22-2000	Astrazeneca AB		
↓	216	WO 00/44744 A1	08-03-2000	Astrazeneca AB		
/G.P./	217	WO 00/45817 A1	08-10-2000	Astrazeneca UK Ltd.		

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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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Art Unit

**Examiner Name**

Attorney Docket Number	29635-714.201
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Sheet	21	of	47
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	227	WO 03/061584 A1	07-31-2003	Curators Uni. Missouri		
	228	WO 89/00566 A1	01-26-1989	Yoshitomi Pharm		
/G P	229	WO 92/04898 A1	04-02-1992	Byk Gulden Lomborg Chem.		

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	231	WO 93/05770 A1	04-01-1993	Fujisawa Pharmaceutical		
	232	WO 94/00112 A1	01-06-1994	Aktiebolaget Astra		
	233	WO 94/02140 A1	02-03-1994	Yoshitomi Pharm		
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PTO/SB/08A (08-03)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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(Use as many sheets as necessary)

Sheet 23

of 47

**Complete if Known**

Application Number	10/783.871
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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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### Art Unit

Examiner Name

Attorney Docket Number	29635-714.201
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## U. S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>3</sup> (if known)	MM-DD-YYYY			
/G.P./	236	WO 95/07913 A1	03-23-1993	Meiji Milk Products Co. Ltd		
↓	237	WO 95/15962 A1	06-15-1995	Astra Aktiebolag		
	238	WO 95/23594 A1	09-08-1995	Gergely		
	239	WO 95/32957 A1	12-07-1995	Astra Aktiebolag		
	240	WO 95/32959 A1	12-07-1995	Astra Aktiebolag		
/G.P./	241	WO 96/01612 A1	01-25-1996	Therapicon S.R.L.		

**Examiner  
Signature**

/Gregg Polansky/

Date  
Considered

12/14/2007

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 24

of 47

**Complete if Known**

Application Number	10/783.871
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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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Attorney Docket Number	29635-714.201
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[illegible]

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		Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>3</sup> (if known)	MM-DD-YYYY			
/G.P./	242	WO 96/01622 A1	01-25-1996	Astra Aktiebolag		
↓	243	WO 96/01623 A1	01-25-1996	Astra Aktiebolag		
	244	WO 96/01624 A1	01-25-1996	Astra Aktiebolag		
↓	245	WO 96/01625 A1	01-25-1996	Astra Aktiebolag		
↓	246	WO 96/02236 A1	02-01-1996	Moore, T		
/G.P./	247	WO 96/16959 A1	06-06-1996	Astra Aktiebolag		

Examiner Signature	/Gregg Polansky/	Date Considered	12/14/2007
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

Sheet	25	of	47
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**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

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[illegible]

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		Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>3</sup> (if known)	MM-DD-YYYY			
/G.P./	248	WO 96/24338 A1	08-15-1996	Astra Aktiebolag		
↓	249	WO 96/24375 A1	08-15-1996	Astra Aktiebolag		
	250	WO 96/38175 A1	12-05-1996	Astra Aktiebolag		
	251	WO 97/02020 A1	01-23-1997	Byk Gulden Lomberg Chem		
	252	WO 97/02021 A1	01-23-1997	Byk Gulden Lomberg Chem		
/G.P.	253	WO 97/09964 A1	03-20-1997	Astra Aktiebolag		

**Examiner  
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/Gregg Polansky/

Date  
Considered

12/14/2007

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

Sheet	26	of	47
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**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	29635-714.201

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[illegible]

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
/G.P./	254	WO 97/25064 A1	07-17-1997	Astra Aktiebolag		
↓	255	WO 97/25065 A1	07-17-1997	Astra Aktiebolag		
	256	WO 97/41114 A1	11-06-1997	Astra Aktiebolag		
	257	WO 97/48380 A1	12-24-1997	Astra Aktiebolag		
	258	WO 98/00114 A2	01-08-1998	Klinge Pharma		
/G.P./	259	WO 98/02368 A1	01-22-1998	Merck Patent		

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/Gregg Polansky/

Date	
Cons	

12/14/2007

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 27 of

**Complete if Known**

Application Number	10/783,871
Filing Date	20-Feb-04
First Named Inventor	Widder, et al.
Art Unit	
Examiner Name	
Attorney Docket Number	

## U. S. PATENT DOCUMENTS

[illegible]

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/G.P.	260	WO 98/16228 A1	04-23-1998	Astra Aktiebolag		
↓	261	WO 98/28294 A1	07-02-1998	Astra Aktiebolag		
↓	262	WO 98/40054 A1	09-17-1998	Astra Aktiebolag		
↓	263	WO 98/50019 A1	11-12-1998	Sage Pharmaceuticals		
↓	264	WO 98/53803 A1	12-03-1998	Astra Aktiebolag		
/G.P.	265	WO 98/54171 A1	12-03-1998	Astra Aktiebolag		

Examiner Signature	/Gregg Polansky/	Date Considered	12/14/2007
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 28

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of 47

47

**Complete if Known**

Application Number	10/783.871
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10783.871

Filing Date	20-Feb-04
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20-Feb-04

First Named Inventor	Widder, et al.
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Widder, et al.

### Art Unit


Examiner Name

Attorney Docket Number	29635-714.201
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/G.P./	266	WO 99/00380 A1	01-07-1999	Astra Aktiebolag		
	267	WO 99/08500 A2	02-25-1999	Astra Aktiebolag		
	268	WO 99/25323 A1	05-27-1999	Andrx Pharmaceuticals		
	269	WO 99/25711 A1	05-27-1999	Astra Aktiebolag		
	270	WO 99/27917 A1	06-10-1999	Byk Gulden Lomborg Chem		
	/G.P./	271	WO 99/29299 A1	07-17-1999	Byk Gulden Lomborg Chem	

**Examiner  
Signature**

/Gregg Polansky/

Date	Considered
11/1/80	11/1/80
11/2/80	11/2/80
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11/5/80	11/5/80
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11/30/80	11/30/80

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Sheet 29

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of

## Complete if Known

Application Number	10/783,871
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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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**Art Unit**

Examiner Name
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Attorney Docket Number

[illegible]

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↓	273	WO 99/32091 A1	07-01-1999	Astra Aktiebolag		
	274	WO 99/32093 A1	07-01-1999	Astra Aktiebolag		
	275	WO 99/45004 A1	09-10-1999	Nicox S.A.		
	276	WO 99/53918 A1	10-28-1999	Eisai Co. Ltd		
	277	WO 99/55705 A1	11-04-1999	Astra Aktiebolag		

Examiner Signature	/Gregg Polansky/	Date Considered	12/14/2007
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**(Use as many sheets as necessary)**

Sheet 30

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**Complete if Known**

Application Number	10/783,871
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Filing Date	20-Feb-04
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First Named Inventor	Widder, et al.
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Art Unit	Unit	Lesson	Activity	Assessment
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		Filing Date	20-Feb-2004
		First Named Inventor	Widder, et al.
		Art Unit	
		Examiner Name	
Sheet 31	of 47	Attorney Docket Number	29635-714.201

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/G.P./	279	ADAMS, S.P., et al., "Comments of the Report of 'Association' of Omeprazole with DNA by Phillips et al.", Mutagenesis, 1992, pp 395-396, Vol. 7, No. 5, Oxford University Press	
	280	AL-ASSI, M.T., et al., "Treatment of Helicobacter Pylori Infection with Omeprazole-Amoxicillin Combination Therapy Versus Rantidine/Sodium Bicarbonate-Amoxicillin", The American Journal of Gastroenterology, 1995, pp. 1411-1414, Vol. 90, No. 9	
	281	ANDERSSON, T., et al., "Pharmacokinetics of (14C) Omeprazole in Patients with Liver Cirrhosis", Clinical Pharmacokinetics, 1993, pp71-78, Vol. 24, No. 1	
	282	ANDERSSON, T., et al., "Pharmacokinetics of Various Single Intravenous and Oral Doses of Omeprazole", European Journal of Clinical Pharmacology, 1990, pp195-197, Vol. 39, No. 2	
	283	ANDERSSON, T., et al., "Pharmacokinetics and Bioavailability of Omeprazole After Single and Repeated Oral Administration in Healthy Subjects", British Journal of Clinical Pharmacology, 1990, pp557-563, Vol. 29 No. 5	
	284	ANDERSSON, T., "Pharmacokinetics, Metabolism and Interactions of Acid Pump Inhibitors: Focus on Omeprazole, Lansoprazole and Pantoprazole", Clinical Pharmacokinetics, 1996, pp9-28, Vol. 31, No. 1	
	285	ANDERSSON, T., et al., "Pharmacokinetic Studies with Esomeprazole, the (S)-Isomer of Omeprazole", Clinical Pharmacokinetics, 2001, pp411-426, Vol. 40, No. 6	
	286	ARVIDSSON, T., et al., "Peak Distortion in the Column Liquid Chromatographic Determination of Omeprazole Dissolved in Borax Buffer", Journal of Chromatography, 1991, pp271-276, Vol. 586, Part 2	
	287	BALABAN, D. et al., "Nasogastric Omeprazole: Effects on Gastric pH in Critically Ill Patients", The American Journal of Gastroenterology, 1997, pp 79-83, Vol. 92, No. 1	
/G.P./	288	BALLARD, E., et al., "Bioequivalence Between Lansoprazole Sachet for Suspension and Intact Capsule", Gastroenterology, 2001, ppA-245, Vol. 120, No. 5, Suppl. 1. Abstract #1276	

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/G.P./	289	ARTURO BALLESTEROS, M., et al., "Bolus or Intravenous Infusion of Ranitidine: Effects on Gastric pH and Acid Secretion", Annals of Internal Medicine, 1990, pp334-339, Vol. 112	
	290	BARIE, P.S. and HARIRI, R.J., "Therapeutic Use of Omeprazole for Refractory Stress-Induced Gastric Mucosal Hemorrhage", Critical Care Medicine, 1992, pp899-901, Vol. 20 No. 6	
	291	BEEKMAN, S.M., "Preparation and Properties of New Gastric Antacids I: Aluminium Hydroxide-Magnesium Carbonate Dried Gels", Journal of the American Pharmaceutical Association, 1960, pp 191-200, Vol. 49	
	292	BENNETT, D.R., and DICKSON, B.D. (eds), "Gastrointestinal Drugs", The American Medical Association Drug Evaluation, The American Medical Association, Chicago, 1973, pp773-827, 2nd Edition, Publishing Sciences Group, Acton, Massachusetts, U.S.A.	
	293	BLUM, A.L., "Therapeutic Approach to Ulcer Healing", The American Journal of Medicine, Aug. 1985, pp 8-14, Vol. 79, Suppl. 2C	
↓	294	BONE, R.C., "Let's Agree on Terminology: Definition of Sepsis", Critical Care Med., 1991, p27, Vol. 19 No. 7	
/G.P./	295	BORRERO, E., et al., "Antacids vs Sucralfate in Preventing Acute Gastrointestinal Tract Bleeding in Abdominal Aortic Surgery", Archives of Surgery, 1986, pp810-812, Vol.121	
*	296	<del>BRUNTON, L.L., "The Pharmacologic Basis of Therapeutics, 1990, New York, p 907"</del>	
/G.P./	297	CANTU, T.G. and KOREK, J.S., "Central Nervous System Reactions to Histamine-2 Receptor Blockers", Annals of Internal Medicine, 1991, pp1027-1034, Vol.114	
/G.P./	298	CAOS, A., et al., "Rabeprazole for the Prevention of Pathologic and Symptomatic Relapse of Erosive or Ulcerative Gastroesophageal Reflux Disease", The American Journal of Gastroenterology 2000, pp 3081-3088, Vol. 95, No. 11	

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/G.P./	299	CARROLL et al., "Nasogastric Administration of Omeprazole for Control of Gastric pH", 10 World Congresses of Gastroenterology, 1994, Abstract #22P, Vol 2	
	300	CEDERBERG, C. et al., "Omeprazole: Pharmacokinetics and Metabolism in Man", Scandinavian Journal of Gastroenterology, 1989, pp 33-40, Vol. 24, Supp. 166	
	301	CEDERBERG, C. et al., "Effect of Once Daily Intravenous and Oral Omeprazole on 24-Hour Intragastric Acidity in Healthy Subjects", Scandinavian Journal of Gastroenterology, 1993, pp 179-184, Vol. 28, No. 2	
	302	CHING, C. and Lam, S., "Antacids- Indications and Limitations", Drugs, pp 305-317, Vol. 47, No. 2	
	303	CIOFFI, W.G. et al., "Comparison of Acid Neutralizing and Non-Acid Neutralizing Stress Ulcer Prophylaxis in Thermally Injured Patients", The Journal of Trauma, 1994, pp541-547, Vol. 36 No. 4	
	304	COOK D.J., et al., "Nosocomial Pneumonia and the Role of Gastric pH: a Meta-Analysis", Chest, 1991, pp7-13, Vol. 100 No. 1	
	305	COOK, D.J. et al., "Risk Factors for Gastrointestinal Bleeding in Critically Ill Patients", New England Journal of Medicine, Feb. 1994, pp377-381, Vol. 330 No. 6	
	306	COOK D.J., et al., Stress Ulcer Prophylaxis in the Critically Ill; a Meta-Analysis", American Journal of Medicine, 1991, pp519-527, Vol. 91	
↓	307	CRILL, C.M. et al., "Upper Gastrointestinal Tract Bleeding in Critically Ill Pediatric Patients", Pharmacotherapy, 1999, pp 162-180, Vol 19, No. 2	
/G.P./	308	CZAJA A.J. et al., "Acute Gastroduodenal Disease After Thermal Injury: an Endoscopic Evaluation of Incidence and Natural History", New England Journal of Medicine, Oct. 1974, pp925-929, Vol. 291 No. 18	

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/G.P./	309	DEAKIN, M. and TEMPLE J.G., "Therapeutic Process- Review XXXIII: Are We Making Progress In the Drug Treatment of Oesophageal Disease?", Journal of Clinical Pharmacy and Therapeutics, 1988, pp365-374, Vol. 13, No. 6	
	310	DI IORIO, B. et al., "Aluminum and Phosphorus Urinary Excretion After Modifying Gastric Acid Secretion in Normal Subjects", Trace Elements and Electrolytes, 1996, pp 47-49, Vol. 13, No. 1	
	311	DIGIACINTO, J.L. et al., "Stability of Suspension Formulations of Lansoprazole and Omeprazole Stored in Amber-Colored Plastic Oral Syringes", Annals of Pharmacotherapy, 2000, pp 600-605, Vol. 34, No.5	
	312	DOAN, T.T. et al., "Comparative Pharmacokinetics and Pharmacodynamics of Lansoprazole Oral capsules and Suspension in Healthy Subjects", American Journal of Health-System Pharmacists, Aug. 2001, pp 1512-1519, Vol. 58, No. 16	
	313	DOBKIN E.D. et al., "Does pH Paper Accurately Reflect Gastric pH?", Critical Care Medicine, 1990, pp985-988, Vol. 18 No. 9	
	314	DRISKS M.R. et al., "Nosocomial Pneumonia in Intubated Patients Given Sucralfate As Compared with Antacids or Histamine Type 2 Blockers. The Role of Gastric Colonization", New England Journal of Medicine, 1987, pp1376-1382, Vol. 317	
	315	EISENBERG, P.G. et al., "Prospective Trial Comparing a Combination pH Probe-Nasogastric Tube with Aspirated Gastric pH in Intensive Care Unit Patients", Critical Care Medicine, 1990, pp1092-1095, Vol. 18	
	316	EKPE, A. and JACOBSEN, T., "Effect of Various Salts on the Stability of Lansoprazole, Omeprazole, and Pantoprazole as Determined by High-Performance Liquid Chromatography", Drug Development and Industrial Pharmacy, 1999, pp1057-1065, Vol. 25, No. 9	
↓	317	ELLIOT, R. "Nasogastric Administration of Omeprazole", The Australian Journal of Hospital Pharmacy, 1998, pp 174-176, Vol. 28, No. 3	
/G.P./	318	FABIAN T.C. et al., "Pneumonia and Stress Ulceration in Severely Injured Patients. A Prospective Evaluation of the Effects of Stress Ulcer Prophylaxis", Feb. 1993, Archives of Surgery, pp185-192, Vol. 128	

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	320	FIDDIAN-GREEN R.G. et al., "Predictive Value of Intramural pH and Other Risk Factors for Massive Bleeding from Stress Ulceration", Gastroenterology, 1983, pp 613-620, Vol.85	
	321	FITTON, A. and WISEMAN, L., "Pantoprazole, A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders", Drugs, Mar. 1996, pp460-482, Vol. 51, No. 3	
	322	FRYKLUND et al., "Function and Structure of Parietal Cells After H <sup>+</sup> - K <sup>+</sup> -ATPase Blockade", American Journal of Physiology, 1988, , ppG399-407, Vol. 254, No. 3 pt 1	
	323	FUCHS, C., "Antacids: Their Function, Formulation, and Evaluation", Drug and Cosmetic Industry, Jun. 1949, Vol. 64 no. 6, pp 692-773	
	324	GAFTER, U. et al., "Thrombocytopenia Associated with Hypersensitivity to Rantidine: Possible Cross-Reactivity with Cimetidine", American journal of Gastroenterology. 1989, pp 560-562, Vol.84 No. 5	
	325	GARNER J.S. et al., "CDC Definitions for Nosocomial Infections, 1988", American Journal of Infection Control, 1988, pp128-140, Vol. 16	
	326	GARNETT, W.R., "Efficacy, Safety, and Cost Issues in Managing Patients with Gastroesophageal Reflux Diseases", American Journal of Hospital Pharmacy, 1993, pp 511-518, Vol 50 Supp. 1	
↓	327	GRAY et al., "Influence of Insulin Antibodies on Pharmacokinetics and Bioavailability of Recombinant Human and Highly Purified Beef Insulins in Insulin Dependant Diabetics", British Medical Journal, Jun 1985, pp 1687-1690, Vol. 290	
/G.P./	328	HARDY, P. et al., "Inhibition of Gastric Secretion by Omeprazole and Efficiency of Calcium Carbonate on the Control of Hyperphosphatemia in Patients on Chronic Hemodialysis", Artificial Organs, 1998, pp 569-573, Vol. 22, No. 7	

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/G.P./	329	HATLEBAKK, J.G. et al., "Lansoprazole Capsules and Amoxicillin Oral Suspension in the Treatment of Peptic Ulcer Disease", Scandinavian Journal of Gastroenterology, 1995, pp 1053-1057, Vol. 30, No. 11	
	330	HEATH et al., "Intragastric pH Measurement Using a Novel Disposable Sensor", Intensive Care Med, 1988, pp 232-235, Vol.14	
	331	HIXSON, "Current Trends in the Pharmacotherapy for Gastroesophageal Reflux Disease", Arch. Intern. Med., 1992, pp 171-723, Vol. 152, No.4.	
	332	HIXSON, et al., "Current Trends in the Pharmacotherapy for Peptic Ulcer Disease", Archives of Internal Medicine, 1992, pp 726-732, Vol. 152, No. 4	
	333	HOLBERT, J.M. et al., "A Study of Antacid Buffers: The Time Factor in Neutralization of Gastric Acidity", Journal of the American Pharmaceutical Association (Scientific Edition), 1947, pp 149-151, Vol. 36.	
	334	HOLT, S. and HOWDEN, C.W., "Omeprazole, Overview and Opinion", Digestive Diseases and Sciences, 1991, pp 385-393, Vol. 36, No. 4	
	335	HORN, J., "The Proton-Pump Inhibitors: Similarities and Differences", Clinical Therapeutics, 2000, pp 266-280, Vol. 22, No. 3	
	336	HOWDEN, C.W. et al., "Oral Pharmacokinetics of Omeprazole", European Journal of Clinical Pharmacology, 1984, pp 641-643, Vol. 26	
	337	HUMPHRIES, T.J. and Merritt, G.J., "Review Article: Drug Interactions with Agents Used to Treat Acid-Related Diseases", Alimentary Pharmacology & Therapeutics, 1999, pp 18-26, Vol. 13, Supp. 3	
/G.P./	338	JUNGNICKEL, P.W., "Pantoprazole: A New Proton Pump Inhibitor", Clinical Therapeutics, 2000, pp 1268-1293, Vol. 22, No. 11	

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		First Named Inventor	Widder, et al.
		Art Unit	
		Examiner Name	
Sheet 37	of 47	Attorney Docket Number	29635-714.201

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/G.P./	339	KAROL, M.D. et al., "Pharmacokinetics of Lansoprazole in Hemodialysis Patients", Journal of Clinical Pharmacology, 1995, pp 815-820, Vol. 35	
	340	KIHIRA, K. et al., "Endoscopic Topical Therapy for the Treatment of Helicobacter Pylori Infection", Journal of Gastroenterology, 1996, pp 66-68, Vol. 31, Suppl IX	
	341	KIILERICH, S. et al., "Effect of Intravenous Infusion of Omeprazole and Rantidine on Twenty-Four Hour Intragastric pH in patients with Duodenal Ulcer", Digestion, 1995, pp 25-30, Vol. 56	
	342	KORPONAY-SZABO, I.R. et al., "High Acid Buffering Capacity of Protein Hydrolysate Infant Formulas", Journal of Pediatric Gastroenterology and Nutrition, August 2000, Vol. 31, Suppl 2, Abstract 956	
	343	KROMER, W. et al., "Differences in pH-Dependant Activation Rate of Substituted Benzimidazoles and Biological in vitro Correlates", Pharmacology, 1998, pp 57-70, Vol. 56	
	344	KROMER, W., "Similarities and Differences in the Properties of Substituted Benzimidazoles: A Comparison Between Pantoprazole and Related Compounds", Digestion, 1995, pp443-454, Vol. 56, No. 6	
	345	LAGGNER, A.N. et al., "Prevention of Upper Gastrointestinal Bleeding in Long Term Ventilated Patients", American Journal of Medicine, 1989, pp 81-84, Vol. 86 Supp. 6A	
	346	LANDAHL S. et al., "Pharmacokinetic Study of Omeprazole in Elderly Healthy Volunteers", Clinical Pharmacokinetics, 1992, pp 496-476, Vol. 23 No. 6	
	347	LARSON G.M. et al., "Gastric Response to Severe Head Injury", American Journal of Surgery, 1984, pp97-105, Vol. 147	
/G.P./	348	LARSON, C., et al., "Bioavailability and Efficacy of Omeprazole Given Orally and by Nasogastric Tube", Digestive Diseases and Sciences, 1996, pp 475-479, Vol. 41, No. 3	

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/G.P./	349	LARSSON, H. et al., "Gastric Acid Antisecretory Effect of Two Different Dosage of Omeprazole During Prolonged Oral Treatment in the Gastric Fistula Dog", 1988, pp 1013-1019, Vol. 23, No. 8	
	350	LASKY, M., "A Prospective Study of Omeprazole Suspension to Prevent Clinically Significant Gastrointestinal Bleeding from Stress Ulcers in Mechanically Ventilated Trauma Patients", The Journal of Trauma: Injury Infection, and Critical Care, 1998, pp 527-533, Vol. 44, No. 3	
	351	LIN, M., et al., "Evaluation of Buffering Capacity and Acid Neutralizing pH Time Profile of Antacids", Journal of the Formosan Medical Association, 1998, pp 704-710, Vol. 97, No. 10	
	352	LIND, C. et al., "Inhibition of Basal and Betazole- and sham-feeding Induced Acid Secretion by Omeprazole in Man", Scandinavian Journal of Gastroenterology, 1986, pp 1004-1010, Vol. 21	
	353	LOCKHART, S.P. and BAXTER, G., "A Lansoprazole Suspension Formulation as an Alternative to Capsules for Oral Administration", World Congresses of Gastroenterology, 1998, P 226, Vol 59 Suppl 3. Abstract #ExhA2074	
	354	LONDONG, W. et al., "Dose-Response Study of Omeprazole on Meal-Stimulated Gastric Acid Secretion and Gastrin-Release", 1983, Gastroenterology, pp 1373-1378, Vol. 85, No. 6	
	355	MACONI, G. et al., "Prolonging Proton Pump Inhibitor-Based Anti-Helicobacter Pylori Treatment From One to Two Weeks in Duodenal Ulcer: Is it worthwhile?", Digest of Liver Disease, 2000, pp 275-280, Vol. 32	
	356	MARRONE, G.C. and SILEN, W., "Pathogenesis, Diagnosis and Treatment of Acute Gastric Mucosal Lesions", 1984, Clinics in Gastroenterology, pp 635-650, Vol.13 No. 2	
	357	MARTIN L.F. et al., "Continuous Intravenous Cimetidine Decreases Stress-Related Upper Gastrointestinal Hemorrhage Without Promoting Pneumonia", Critical Care Medicine, 1993, pp 19-39, Vol. 21 No. 1	
/G.P./	358	MARTIN L.F. et al., "Stress Ulcers and Organ Failure in Intubated Patients in Surgical Intensive Care Units", Annals of Surgery, 1992, pp332-337, Vol.215 No. 4	

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	360	MAXWELL, S.L. et al., "Control of Gastric pH in A Critical Care Unit: Physician Behavior and Pharmacologic Effectiveness", The American Review of Respiratory Disease, 1991, ppA482, Vol. 143, No. 4(Part 2)	
	361	McANDREWS, K.L. and Eastham J.H., "Omeprazole and Lansoprazole Suspensions for Nasogastric Administration", American Journal of Health-System Pharmacy, 1999, pp81, Vol. 56	
	362	McTAVISH, D. et al., "Omeprazole: An Updated Review of its Pharmacology and Therapeutic Use in Acid-Related Disorders", Drugs, 1991, pp138-170, Vol. 41 No. 1	
	363	Meiners, D. et al., "Evaluation of Various Techniques to Monitor Intragastric pH", Archives of Surgery, 1982, pp 288-291, Vol. 117	
	364	METZLER, M., "Advances in the Use of PPI's from Efficacy to Effectiveness", Presentation: Simplified Omeprazole Suspension", 1999	
	365	MOHIUDDIN, M.A. et al., "Effective Gastric Acid Suppression After Oral Administration of Enteric-Coated Omeprazole Granules", Digestive Diseases and Sciences, 1997, pp 715-719, Vol. 42, No. 4	
	366	NAKAGAWA, A. et al., "Lansoprazole: Phase I Study of Lansoprazole (AG-1749) Antiulcer Agent", Abstract in English; Text in Japanese, 1991, pp33-34	
↓	367	NAKAMURA, M. et al., "Effect of Combined Administration of lansoprazole and Sofalcone on Microvascular and Connective Tissue Regeneration after Ethanol-Induced Mucosal Damage", Journal of Clinical Gastroenterology, 1998, pp S170-177, Vol. 27 Supp. 1,	
/G.P./	368	NAUNTON, M., et al., "Overuse of Proton Pump Inhibitors", Journal of Clinical Pharmacy and Therapeutics", 2000, pp 333-340, Vol. 25	

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/G.P./	369	OH, M.S. and CARROLL H.J., "Electrolyte and Acid-Base Disorders", The Pharmacologic Approach to the Critically Ill Patient, 1994, pp957-968, 3rd Edition, Williams and Wilkins, Baltimore, U.S.A	
	370	OOSTERHUIS, B and JONKMAN, J.H.G., "Omeprazole: Pharmacology, Pharmacokinetics and Interactions", Digestion, 1989, pp 9-17, Vol. 44, Suppl 1	
	371	OSLER, P. et al., "Effect of Omeprazole on the Phosphate-Binding Capacity of Calcium Carbonate", Nephron, 1995, pp 89-90, Vol. 69	
	372	OSTRO, M.J. et al. "Control of Gastric pH with Cimetidine: Boluses Versus Primed Infusions", Gastroenterology, 1985, pp 532-537, Vol. 89 No. 3	
	373	PAUL, J., et al., "Pantoprazole Bicarbonate Suspension(PBS) Provides Oral Bioavailability Comparable to Tablet", Critical Care Medicine, 2001, 30th International Educational and Scientific Symposium, A563	
	374	PECKMAN, H.J., "Alternative Method for Administering Proton-Pump Inhibitors Through Nasogastric Tubes", American Journal of Health Systems Pharmacy, 1999, pp1020, Vol 56	
	375	PEURA, D.A. and JOHNSON, L.F. "Cimetidine for Prevention and Treatment of Gastroduodenal Mucosal Lesions in Patients in an Intensive Care Unit", Annals of Internal Medicine, 1985, pp173-177, Vol. 103 No. 2	
	376	PHILLIPS, J. "Stress-Related Mucosal Damage- Optimizing Drug Therapy", a presentation, 1997	
	377	PHILLIPS, J. and METZLER, M., "Simplified Omeprazole Solution for the Prophylaxis of Stress-Related Mucosal Damage in Critically Ill Patients", Critical Care Medicine, 1994, p A53, Vol. 22 No. 1	
/G.P./	378	PHILLIPS, J.O. et al., "A Prospective Study of Simplified Omeprazole Suspension for the Prophylaxis of Stress-Related Mucosal Damage", Critical Care Medicine, 1996, pp 1793-1800, Vol. 24, No. 11	

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	380	PHILLIPS, "Simplified Omeprazole Solution-(S.O.S)- Pharmacokinetic/Pharmacodynamic Study in Patients at Risk for Stress Related Mucosal Damage(SRMD)" Project #5122, 1994	
	381	PHILLIPS, J., "Overview of Omeprazole Suspension-From Efficacy to Effectiveness Alternative Dosing of PPI's", 1998, a presentation	
	382	PHILLIPS, J., "Overview of Omeprazole Suspension-Problems with Administering Granules", 1999/2000, a presentation	
	383	PHILLIPS, J., "Simplified Omeprazole Suspension (SOS)", 1998, a presentation	
	384	PHILLIPS, J., "Stress-Related Mucosal Damage Optimizing Drug Therapy in the 1990's" presented by Phillips at University of Missouri Surgical Society Scientific Program, 1994	
	385	PHILLIPS, J., "Update on Acid-Related Disorders-Optimizing Pharmacotherapy for the 1990's", a presentation, 1996	
	386	PHILLIPS, J.O., et al., "The Stability of Simplified Omeprazole Suspension(SOS)", Critical Care Medicine, 1998, p A101, Vol.26, No. 1(Suppl), Abstract No. 221	
✓	387	PHILLIPS, J.O. et al., "A Multicenter, Prospective, Randomized Clinical Trial of Continuous Infusion I.V. Rantidine vs. Omeprazole Suspension in the Prophylaxis of Stress Ulcers", Crit Care Med, 1998, pp A101, Vol. 26, No. 1(Suppl) Abstract no. 222	
/G.P./	388	PHILLIPS, J.O., "The Stability of Simplified Lansoprazole Suspension(SLS)" Gastroenterology, Abstract G0382, Vol. 116, No. 4	

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/G.P./	389	PICKWORTH, K.K. et al., "Occurrence of Nosocomial Pneumonia in Mechanically Ventilated Trauma Patients: A Comparison of Sucralfate and ranitidine", Critical Care Medicine, 1993, pp1856-1862, Vol. 21 No. 12	
	390	PILBRANT, A. and CEDERBERG, C. et al., "Development of an Oral Formulation of Omeprazole." Scandinavian Journal of Gastroenterology, 1985, pp113-120, Vol. 20 Supp 108	
	391	PILBRANT, A. "Principles for Development of Antacids", Scandinavian Journal of Gastroenterology, 1982, pp 32-36, Vol. 75	
	392	PIPKIN, G.A. and MILLS, J.G., "Onset of Action of Antisecretory Drugs: Beneficial Effects of a Rapid Increase in Intragastric pH in Acid Reflux Disease", Scandinavian Journal of Gastroenterology., 1999, pp 3-8, Suppl. 230	
	393	PRICHARD, P.J. et al., "Omeprazole: A Study of its Inhibition of Gastric pH and Oral Pharmacokinetics After Morning or Evening Dosage", Gastroenterology, 1985, pp 64-69, Vol. 88	
	394	PRIEBE, H. and SKILLMAN, J.J., "Methods of Prophylaxis in Stress Ulcer Disease", World Journal of Surgery, 1981, pp223-233, Vol. 5 No. 2	
	395	QUERCIA, R.A. et al., "Stability of Omeprazole in an Extemporaneously Prepared Oral Liquid", American Journal of Health System Pharmacy, 1997, pp 1833-1836, Vol. 54, No. 16	
	396	REGARDH, C.G. et al., "The Pharmacokinetics of Omeprazole in Humans—a Study of Single Intravenous and Oral Doses", Therapeutic Drug Monitoring, 1990, pp163-172, Vol. 12, No. 2	
↓	397	REGARDH, et al., "Pharmacokinetics and metabolism of omeprazole in animals and man—an overview." Scandinavian Journal of Gastroenterology Suppl. 1985 pp79-94. Vol 108	
/G.P./	398	RODRIGO, J.M. and PONCE, J., "Therapeutic Approach to Peptic Ulcer Relapse", Methods and Findings in Experimental and Clinical Pharmacology, 1989, pp 131-135, Vol. 11 Suppl. 1	

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		Application Number	10/783,871
		Filing Date	20-Feb-2004
		First Named Inventor	Widder, et al.
		Art Unit	
		Examiner Name	
Sheet	43	of	47
		Attorney Docket Number	29635-714.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/G.P./	399	ROY, P.K. et al., "Zollinger-Ellison Syndrome-Clinical Presentation in 261 Patients", Medicine, 2000, pp 379-411, Vol. 79, No. 6	
	400	RYAN, P. et al., "Nosocomial Pneumonia During Stress Ulcer Prophylaxis with Cimetidine and Sucralfate", 1993, Archives of Surgery, pp1353-1357, Vol. 128	
	401	SAX, M.J. "Clinically Important Adverse Effects and Drug Interactions with H2-Receptor Antagonists: an Update", Pharmacotherapy, 1987, pp 110S-115S, Vol. 7 No. 6 pt. 2	
	402	SCHEPP, W., "Stress Ulcer Prophylaxis: Still a Valid Option in the 1990s?", Digestion, 1993, pp189-199, Vol. 54	
	403	SCHMASSMANN, A. et al., "Antacid Provides Better Restoration of Glandular Structures Within the Gastric Ulcer Scar than Omeprazole", Gut, 1994, pp 869-904, Vol. 35, No.7	
	404	SCHMASSMANN, A. et al., "Antacids in Experimental Gastric Ulcer Healing: Pharmacokinetics of Aluminum and Quality of Healing", European Journal of Gastroenterology & Hepatology, 1993, pp S111-S116, Vol. 5, Suppl. 3	
	405	SHUMAN, R.B. et al., "Prophylactic Therapy for Acute Ulcer Bleeding: a Reappraisal", Annals of Internal Medicine, 1987, pp562-567, Vol. 106	
	406	SCHUSTER, D.P. "Stress Ulcer Prophylaxis: in Whom? with What?", Critical Care Medicine, 1993, pp4-6, Vol. 21,	
↓	407	SECHET, A. et al., "Role of the Time of Administration of Calcium Carbonate in the Control of Hyperphosphemia in Patients on Maintenance Hemodialysis", Nephrologie, 1999, pp 209-212, Vol. 20, No. 4	
/G.P./	408	SECHET, A. et al., "Inhibition of Gastric Secretion by Omeprazole and Efficacy of Calcium Carbonate in the Control of Hyperphosphatemia in Patients on Maintenance Hemodialysis", Nephrologie, 1999, pp 213-216, Vol.20, No. 4	

Examiner Signature	/Gregg Polansky/	Date Considered	12/14/2007
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/G.P./	409	SHARMA V.K. et al., "The Effects on Intragastric Acidity of Per-Gastrostomy Administration of an Alkaline Suspension of Omeprazole", Alimentary Pharmacology & Therapeutics, 1999, pp 1091-1095, Vol. 13	
	410	SHARMA, V.K. et al., "Oral Pharmacokinetics of Omeprazole and Lansoprazole After Single and Repeated Doses as Intact Capsules or as Suspensions in Sodium Bicarbonate", Alimentary Pharmacology & Therapeutics, 2000, pp 887-892, Vol. 14, No. 7	
	411	SHARMA, V.K. et al., "The Pharmacodynamics of Lansoprazole Administered via Gastrostomy as Intact, Non-Encapsulated Granules", Alimentary Pharmacology & Therapeutics, 1998, pp 1171-1174, Vol. 12	
	412	SHARMA, V.K. et al., "Simplified Lansoprazole Suspension-A Liquid Formulation of Lansoprazole-Effectively Suppress Intragastric Acidity When Administered Through a Gastrostomy", American Journal of Gastroenterology, 1999, pp 1813-1817, Vol. 94, No. 7	
	413	SHARMA, V.K., "Comparison of 24-Hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole", American journal of Health System Pharmacy 1999, pp S180-S21, Vol. 56, Suppl 4	
	414	SHARMA, V.K. et al., "Effect on 24-Hour Intragastric Acidity of Simplified Omeprazole Solution(SOS) Administered via Gastrostomy", American Journal of Gastroenterology, 1997, p1625, Vol. 92, No. 9, Abstract #169	
	415	SHARMA, V.K., "Simplified Lansoprazole Suspension(SLS): A Proton Pump Inhibitor(PPI) in a Liquid Formulation that Works", American Journal of Gastroenterology, Sep. 1998, pp1647, Abstract #153	
	416	SIEPLER, J.K. et al., "Selecting Drug Therapy for Patients with Duodenal Ulcers", Clinical Pharmacy, 1990, pp 463-467, Vol. 9, No. 6	
	417	SIEPLER, J.K., "A Dosage Alternative for H-2 Receptor Antagonists, Continuous-Infusion", Clinical Therapeutics, 1986, pp24-33, Vol. 8 Suppl A	
/G.P./	418	SIH, J.C. et al., "Studies on (H(+)-K+)-ATPase Inhibitors of Gastric Acid Secretion. Prodrugs of 2-[(2-Pyridinylmethyl)sulfinyl] benzimidazole Proton-pump Inhibitors", Journal of Medical Chemistry 1991, pp 1049-1062, Vol. 34, No. 3	

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		Filing Date	20-Feb-2004
		First Named Inventor	Widder, et al.
		Art Unit	
		Examiner Name	
Sheet 45	of 47	Attorney Docket Number	29635-714.201

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/G.P./	419	SIMMS, H. et al., "Role of Gastric Colonization in the Development of Pneumonia in Critically Ill Trauma Patients: Results of a Prospective Randomized Trial", Journal of Trauma, 1991, pp 531-537, Vol. 31 No. 4	
	420	SKILLMAN, J.J. et al., "Respiratory Failure, Hypotension, Sepsis and Jaundice: a Clinical Syndrome Associated with Lethal Hemorrhage from Acute Stress Ulceration of the Stomach", American Journal of Surgery, 1969, pp 523-530, Vol. 117	
	421	SKILLMAN, J.J. et al., "The Gastric Mucosal Barrier: Clinical and Experimental Studies in Critically Ill and Normal Man, and in the Rabbit", Annals of Surgery, 1970, 564-584, Vol. 172 No. 4	
	422	SMYTHE, M.A. and ZAROWITZ, B.J., "Changing Perspectives of Stress Gastritis Prophylaxis", The Annals of Pharmacotherapy, 1994, pp1073-1085, Vol. 28	
	423	SPENCER, C.M. and FAULDS, D., "Esomeprazole", Drugs 2000, August 2000, pp 321-329, Vol. 60, No. 2	
	424	SPYCHAL, R.T. & WICKMAN, N.W.R., "Thrombocytopenia Associated with Rantidine", British Medical Journal, 1985, p 1687, Vol. 291	
	425	STRATFORD, M.R.L. et al., "Nicotinic Pharmacokinetics in Humans: Effect of Gastric Acid Inhibition, Comparison of Rectal vs. Oral Administration and the Use of Saliva for Drug Monitoring", British Journal of Cancer, 1996, pp 16-21, Vol. 74, No. 1	
	426	TABATA, T. et al., "Stabilization of a New Antiulcer Drug(Lansoprazole) in the Solid Dosage Forms", Drug Development and Industrial Pharmacy, 1992, pp1437-1447, Vol. 18, No. 13	
	427	TAKEUCHI, K. et al., "Effects of Pantoprazole, a novel H <sup>+</sup> /K <sup>+</sup> -ATPase Inhibitor, on Duodenal Ulcerogenic and Healing Responses in Rats: a Comparative Study with Omeprazole and Lansoprazole", Journal of Gastroenterology and Hepatology, 1999, pp251-257, Vol. 14, No. 3	
/G.P./	428	TANAKA, M. et al., "Differential Stereoselective Pharmacokinetics of Pantoprazole, a Proton Pump Inhibitor in Extensive and Poor Metabolizers of Pantoprazole- A Preliminary Study", Chirality, 1997, pp 17-21, Vol. 9	

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Sheet 46	of 47	Attorney Docket Number	29635-714.201

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	430	THOMSON, A.B.R., "Are the Orally Administered Proton Pump Inhibitors Equivalent? A Comparison of Lansoprazole, Omeprazole, Pantoprazole, and Rabeprazole". Current Gastroenterology Reports, 2000, pp482-493, Vol. 2	
	431	TRYBA, M., "Risk of Acute Stress Bleeding and Nosocomial Pneumonia in Ventilated Intensive Care Patients, Sucralfate vs. Antacids", American Journal of Medicine, 1987, pp 117-124, Vol. 87 Suppl. 3B	
	432	TRYBA, M., "Stress Ulcer Prophylaxis-Quo Vadis?", Intensive Care Medicine, 1994, pp 311-313, Vol. 20	
	433	TYTGAT, G.N.J., "Drug Therapy of Reflux Oesophagitis: An Update.", Scandinavian Journal of Gastroenterology, 1989, pp38-49, Vol. 24, Suppl 168	
	434	VIAL, T. et al., "Side Effects of Rantidine", Drug Safety, 1991, pp 94-117, Vol. 6 No. 2	
	435	VINCENT, J. et al., "Concurrent Administration of Omeprazole and Antacid Does Not Alter the Pharmacokinetics of Doxetilide in Healthy Subjects", Clinical Pharmacology & Therapeutics, 1996, p 182, Vol. 59, No. 2, Abstract P11-93	
	436	WADE, L.G., Organic Chemistry, 1987, pp349-350, Prenitice-Hall, Inc., New Jersey, U.S.A	
	437	WALAN, A., "Pharmacological Agents for Peptic Ulcer Disease", Scandinavian Journal Gastroenterology, Suppl., 1984, p 1, Vol. 19, No. 98	
/G.P./	438	WALLMARK, B. et al., "The Relationship Between Gastric Acid Secretion and Gastric H <sup>+</sup> /K <sup>+</sup> -ATPase Activity", Journal of Biological Chemistry, 1985, 13681-13684, Vol. 260 No. 25	

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	440	WILDER-SMITH, C.H. and MERKI, H.S., "Tolerance During Dosing with H2 Receptor Antagonists, An Overview", 1992, Scandinavian Journal of Gastroenterology, pp 14-19, Vol. 27 (Suppl 193)	
	441	WHIPPLE, J. et al., "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements through the Nasogastric Tube", Critical Care Medicine, 1995, pp A69, Vol. 28, No.1(Suppl)	
	442	YAMAKAWA, T. et al., "Synthesis and Structure-Activity Relationships of Substituted 2-(2-Imidazolylsulfinyl)methyl anilines as a New Class of Gastric H+/K(+)-ATPase Inhibitors. II.", Chemical and Pharmaceutical Bulletin, 1992, pp675-682, Vol. 40, No. 3	
	443	YASUDA, S. et al., "Antacids Have No Influence of the Pharmacokinetics of Rabeprazole, A New Proton Pump Inhibitor, in Healthy Volunteers", International Journal of Clinical Pharmacology and Therapeutics, 1999, pp 249-253, Vol. 37, No. 5	
	444	ZINNER, M.J. et al., "The Prevention of Gastro-Intestinal Tract Bleeding in Patients in an Intensive Care Unit", Surgery, Gynecology and Obstetrics, pp 214-220, Vol. 153	
↓	445	"Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", Chapter 37, pp 907-909	
/G.P./	446	"Buffered and Isotonic Solutions", Physical Pharmacy, pp 169-189, Chap.8	
	<del>447</del>	<del>"Pharmacotherapy Related Outcomes Group Researching Effective Stress Ulcer Strategies", Overview of Omeprazole Suspension 2000, a presentation</del>	
	<del>448</del>	<del>"Stress Ulcer Prophylaxis in the 21st Century", Overview of Omeprazole Suspension 2001, a presentation.</del>	

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			Filing Date	February 20, 2005	
			First Named Inventor	Bonnie Hepburn	
			Art Unit	1614	
Examiner Name			Polansky		
Sheet	2	of	7	Attorney Docket Number	29635-714.201

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/G.P./	25	US-2002/0068088 A1	06-06-2002	Gruber	
	26	US-2002/0039597 A1	04-04-2002	Ukai et al.	
	27	US-2002/0012680 A1	01-31-2002	Patel et al.	
	28	US-2002/0025342 A1	02-28-2002	Linder et al.	
	29	US-5,026,560	06-25-1991	Makino et al.	
	30	US-5,433,959	07-18-1995	Makino et al.	
	31	US-5,464,632	11-07-1995	Cousin et al.	
	32	US-6,328,994	12-11-2001	Shimuzu et al.	
	33	US-6,047,829	04-11-2000	Johnstone et al.	
	34	US-5,536,735	07-16-1996	Takechi et al.	
	35	US-5,635,520	06-03-1997	Uda	
	36	US-5,824,339	10-20-1998	Shimizu et al.	
	37	US-5,846,562	12-08-1998	Yanai et al.	
	38	US-5,948,773	09-07-1999	Akiyama et al.	
	39	US-6,169,102 B1	01-02-2001	Kanamaru et al.	
	40	US-6,299,904 B1	10-09-2001	Shimizu et al.	
	41	US-6,319,904	11-20-2001	Akiyama et al.	
	42	US-6,462,058 B1	10-08-2002	Fujishima et al.	
/G.P./	43	US-6,586,004 B2	07-01-2003	Shimizu et al.	

## FOREIGN PATENT DOCUMENTS

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Examiner Signature	/Gregg Polansky/	Date Considered	12/14/2007
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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/783,871
				Filing Date	February 20, 2005
				First Named Inventor	Bonnie Hepburn
				Art Unit	1614
Examiner Name	Polansky				
Sheet	3	of	7	Attorney Docket Number	29635-714.201

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/G.P./	44	US-6,740,339 B1	05-25-2004	Ohkouchi et al.	
	45	US-2001/0009678 A1	07-26-2001	Toshihiro et al.	
	46	US-2001/00110825 A1	08-02-2001	Shimizu et al.	
	47	US-2001/0027192 A1	10-04-2001	Akiyama et al.	
	48	US-2002/0142034 A1	10-03-2002	Shimizu et al.	
	49	US 2003/0045724 A1	03-06-2003	Fujishima et al.	
	50	US 2003/0181487 A1	09-25-2003	Kamiyama et al.	
	51	US-2004/0005362 A1	01-08-2004	Taneja	
	52	US-2004/0018239 A1	01-29-2004	Ishida et al.	
	53	US-2004/0039027 A1	02-26-2004	Kamiyama et al.	
	54	US-2004/0048898 A1	03-11-2004	Fujishima et al.	
	55	US-2004/0049045 A1	03-11-2004	Hashimoto et al.	
	56	US-2004/0052854 A1	03-18-2004	Yoshinari et al.	
	57	US-2004/0082971 A1	04-29-2004	Fujishima et al.	
	58	US-2004/0097539 A1	05-20-2004	Terashita et al.	
	59	US-2004/0097555 A1	05-20-2004	Ohkawa et al.	
	60	US-2004/0131675 A1	07-08-2004	Yamamoto et al.	
✓	61	US-2003/0235628 A1	12-25-2003	Taneja et al.	
	62	US-2004/0006109 A1	01-08-2004	Taneja	
/G.P./	63	US-2004/0081671 A1	04-29-2004	Taneja	

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/G.P./	64	US-2004/0081700 A1	04-29-2004	Taneja	
	65	US-2004/0082618 A1	04-29-2004	Taneja	
	66	US-2004/0121004 A1	06-24-2004	Taneja	
	67	US-2004/0131676 A1	07-08-2004	Taneja	
	68	US-2002/0146451 A1	10-10-2002	Sharma et al.	
	69	US-4,808,596	02-28-1989	Matsuishi et al.	
	70	US-2003/0096845 A1	05-22-2003	Whittle et al.	
	71	US-2003/0088106	05-08-2003	Whittall et al.	
	72	US-4,628,098	12-09-1986	Nohara et al.	
	73	US-4,689,333	07-25-1987	Nohara et al.	
	74	US-5,013,743	05-07-1991	Iwahi et al.	
	75	US-5,045,321	09-03-1991	Makino et al.	
	76	US-5,093,132	03-03-1992	Makino et al.	
	77	US-6,123,962	9-26-2000	Makino et al.	
	78	US-6,608,092	08-19-2003	Fujishima et al.	
	79	US-6,664,276	12-16-2003	Fujishima et al.	
	80	US-6,740,339	05-25-2004	Ohkouchi et al.	
	81	US-2001/0010825A1	08-02-2001	Shimizu et al.	
	82	US-2004/0082791A1	04-29-2004	Yoshinari et al.	
/G.P./	83	US-2002/0192299A1	12-19-2002	Rajneesh et al.	

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/G.P./	84	US-6,235,311	05-22-2001	Ullah et al.	
	85	US-6,248,363	07-19-2001	Patel et al.	
	86	US-2003/0191159 A1	10-09-2003	Phillips	
	87	US-6,030,988	02-29-2000	Gillis et al.	
	88	US-6,262,085	07-17-2001	Whittle et al.	
	89	US-6,262,086	07-17-2001	Whittle et al.	
	90	US-6,268,385	07-31-2001	Whittle et al.	
	91	US-6,328,993	12-11-2001	Linder et al.	
	92	US 2001/0048946	12-06-2001	Ghebre-Sellassie	
/G.P./	93	US 2004/0248942	12-09-2004	Hepburn et al.	

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Sheet	6	of	7	Attorney Docket Number	29635-714.201

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	94	Dialog patent search re: omeprazole & specific coating, U.S. patents bibliographic – titles, claims, abstracts only, May 30, 2003, p. 1-211.	
	95	Dialog search re: omeprazole & specific coating, EP, PCT full text files, May 30, 2003, p. 212-804.	
	96	Dialog patent search re: omeprazole & specific coating, May 27, 2003, 154 pages.	
	97	Dialog patent search re: omeprazole & specific coating, May 29, 2003, 59 pages.	
	98	Nerac search re: Question No. 1116119.009, Omeprazole or Proton Pump Inhibitor and Coating (negate enteric)	
	99	Nerac search re: omeprazole and ethocel (ETC), Question No. 1116119.014, May 2003, 38 pages.	
	100	Nerac search re: omeprazole/microencapsulation/HP, Question No. 1116119.008, May 2003, 12 pages.	
	101	Nerac search re: omeprazole and RD100, Question No. 1116119.017, May 2003, 12 pages.	
	102	Nerac search re: omeprazole and (opadry or HPMC), Question No. 1116119.016, May 2003, 47 pages.	
	103	Nerac search re: omeprazole and kollicoat IR, Question No. 1116119.011, May 2003, 2 pages.	

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	104	<del>Norac search re: omeprazole and ethocel, Question No. 1116119.015, May 2003, 3 pages.</del>	
/G.P./	105	PHILLIPS, J.O. et al., "A Randomized, Pharmacokinetic and Pharmacodynamic, Cross-Over Study of Duodenal or Jejunal Administration Compared to Nasogastric Administration of Omeprazole Suspension in Patients at Risk for Stress Ulcers," American Journal of Gastroenterology (2001), Vol 96, No. 2, pp. 367-372.	

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/G.P./	1	US-2004-0170750	09-02-2004	Bunick et al.	
/G.P./	2	US-2004-0146559	7-29-2004	Sowden et al.	

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				Application Number	10/783,871	
				Filing Date	2/20/04	
				First Named Inventor	Bonnie HEPBURN	
				Art Unit	1614	
Examiner Name	Polansky					
Sheet	1	Of	1	Attorney Docket Number	29635-714.201	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/G.P./	1.	US-2005-0054682	03-10-2005	Phillips	

Examiner Signature	/Gregg Polansky/	Date Considered	12/14/2007
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